III. 510(K) SUMMARY K024076

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Submitter's Name: HDC Maquinolas, LLC
129A Citizens Blvd.
Simpsonville, KY 40067
Telephone: (502) 722-5939

Contact person: Mr. Hugh Doss, Manager

Date of Summary: December 6, 2002

Device Name: MAKY 21.1 Dialyzer Reprocessing System

Device Classification Name: Dialyzer Reprocessing System (78 LIF)

Device Description: The MAKY 21.1 Dialyzer Reprocessing System is designed and manufactured to reprocess standard, high efficiency, and high flux hollow-fiber dialyzers. Each type of dialyzer can be processed by one of two pre-programmed cycles, or by a custom cycle configured by HDC Maquinolas, LLC. Custom cycles meet the same minimum requirements as the pre-programmed cycles. The MAKY 21.1 may be configured to utilize one of two approved cleaning agents (peracetic acid, bleach), and one of three approved disinfection agents (peracetic acid, glutaraldehyde, formaldehyde). The MAKY 21.1 will automatically dilute the cleaning and disinfection agents, with the exception of glutaraldehyde, which must be diluted by the user.

Intended Use: The MAKY 21.1 is indicated for use in automating the in-vitro rinsing, cleaning, testing and disinfection of hollow fiber type hemodialyzers in accordance with the AAMI Recommended Practice for Reuse of Hemodialyzers when such automation is chosen for use by a prescribing physician. It is also indicated for record keeping of these functions.

Legally Marketed Devices to which Equivalence is Claimed: The legally marketed predicate devices are:

- Minntech Corporation Renatron II Dialyzer Reprocessing System (K904210), determined to be substantially equivalent to a legally marketed (preAmendment) device on November 27, 1990.
- Mesa Medical, Inc. Echo MM1000 Dialyzer Reprocessing System (K834447), determined to be substantially equivalent to a legally marketed (preAmendment) device on December 16, 1983.

Descriptive Summary of Technological Characteristics and Those of Predicate Devices: The features of the MAKY 21.1 are equivalent to those of other dialyzer reprocessing systems currently in distribution in the United States.

Performance Data: Each function of the MAKY 21.1 System was tested to see if it performed as intended. Any errors or failures detected during testing were corrected. In-vitro testing was also performed to assure the MAKY 21.1 properly diluted the cleaner/disinfectant concentrate to the in-use concentrations of active ingredients. All materials have been tested for material compatibility with the chemicals used in the system as specified in the labeling. The results from these tests show that the MAKY 21.1 performed as expected.

Conclusion: The information and data provided in this 510(k) Notification establish that the MAKY 21.1 Dialyzer Reprocessing System is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2003

HDC Maquinolas, LLC
c/o Lori Kleinschrodt Holder, RAC, CQE, CQMgr.
Regulatory Affairs Consultant
8508 Beacon Bend Lane
PEARLAND TX 77584

Re: K024076
Trade/Device Name: MAKY 21.1 Dialyzer Reprocessing System
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LIF
Dated: June 27, 2003
Received: June 30, 2003

Dear Ms. Holder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

II. INDICATIONS FOR USE STATEMENT

December 6, 2002

510(k) Number: K024076

Device Name: MAKY 21.1 Dialyzer Reprocessing System

Indications for Use: The MAKY 21.1 is indicated for use in automating the in-vitro rinsing, cleaning, testing and disinfection of hollow fiber type hemodialyzers in accordance with the AAMI Recommended Practice for Reuse of Hemodialyzers when such automation is chosen for use by a prescribing physician. It is also indicated for record keeping of these functions.

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024076

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)